# In the United States Court of Federal Claims

# OFFICE OF SPECIAL MASTERS No. 20-1858V UNPUBLISHED

GABRIEL FLORES,

Petitioner,

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: May 24, 2023

Special Processing Unit (SPU); Entitlement to Compensation; Ruling on the Record; Findings of Fact; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA);

Brynna Gang, Kraus Law Group, LLC, Chicago, IL, for petitioner.

Andrew Henning, U.S. Department of Justice, Washington, DC, for respondent.

# **RULING ON ENTITLEMENT<sup>1</sup>**

On December 15, 2020, Gabriel Flores ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*<sup>2</sup> (the "Vaccine Act"). Petitioner alleges that he suffered a shoulder injury related to vaccine administration ("SIRVA") caused by an influenza ("flu") vaccine administered on September 28, 2019. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters. For the reasons described below, I find that Petitioner is entitled to compensation.

<sup>&</sup>lt;sup>1</sup> In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

<sup>&</sup>lt;sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

# I. Relevant Procedural History

After the claim's initiation, Respondent indicated that he was interested in a litigative risk settlement. ECF No. 23. The parties were unable to reach an agreement, however, so Petitioner submitted a motion for a ruling on the record on June 24, 2022. Petitioner's Motion for Ruling on the Record and Memorandum in Support ("Mot."), ECF No. 30. Petitioner argues therein that he meets the Table Claim requirements for a SIRVA. *Id.* at 10-13. Petitioner has also briefed damages, and requests \$85,000.00 for pain and suffering, and \$684.40 for out-of-pocket medical expenses. *Id.* at 13-19.

Respondent opposed compensation on August 23, 2022. Respondent's Response to Petitioner's Motion for Ruling on the Record ("Opp."), ECF No. 35. Respondent argues that Petitioner does not satisfy the Table requirements for a SIRVA, because he cannot establish that onset of his shoulder pain occurred within forty-eight hours of vaccine administration, and because his pain was reported outside of his shoulder. *Id.* at 12. Petitioner filed a reply on September 6, 2022. Petitioner's Reply in Support of his Motion for Ruling on the Record and Damages Award ("Reply"), ECF No. 36.

#### II. Petitioner's Medical Records

Petitioner received a flu vaccine in his left shoulder on September 27, 2019. Ex. 1 at 2. There is no history of prior left shoulder pain or issues.

On December 4, 2019 (more than two months post-vaccination), Petitioner presented to Dr. Amit Agarwal for a routine wellness exam. Ex. 2 at 4. At this time, Petitioner reported "left shoulder pain starting after receiving a flu shot." Ex. 2 at 4. This record also states that the "pain starts in his shoulder and travels down his arm." *Id.* An examination showed left anterior shoulder pain, decreased range of motion, but normal strength. *Id.* at 5. Ibuprofen and cyclobenzaprine (a muscle relaxant) were prescribed. *Id.* Petitioner returned to Dr. Agarwal on December 23, 2019, for a follow-up regarding his shoulder pain. *Id.* at 2. Petitioner stated the "pain started after receiving [sic] flu vaccine" and it had not improved since the last visit. *Id.* 

Approximately two weeks later, on January 7, 2020, Petitioner presented to Dr. Daniel Troy, an orthopedic surgeon. Ex. 4 at 13. Dr. Troy noted that Petitioner complained of localized left shoulder pain "that occurs occasionally." *Id.* He also reported tingling and numbness in his first and second digits, shoulder pain, and elbow pain. *Id.* Further, Petitioner stated "this all started in September after he received a flu shot…." *Id.* Dr. Troy also set forth in this record that Petitioner "has been trying to work through it but ever since then has been having discomfort." *Id.* An examination showed significant and

severe signs of impingement. *Id.* Petitioner was assessed with severe rotator cuff tendinitis and left elbow lateral epicondylitis. *Id* at 13-14.

Petitioner underwent an MRI on January 30, 2020, and the resulting images were deemed "highly suggestive of adhesive capsulitis/frozen shoulder". Ex. 4 at 10. His diagnosis now included lateral epicondylitis, left shoulder pain, and left shoulder adhesive capsulitis. *Id*.

A follow-up on January 31, 2020, with an orthopedic physician assistant in Dr. Troy's office noted that the Petitioner continued to report pain in his elbow, but "the majority of his pain [was] located in the left shoulder." Ex. 4 at 9. The record also notes that Petitioner "had this pain ever since receiving a flu shot in September...." *Id.* He was assessed with left elbow pain secondary to epicondylitis, left shoulder pain secondary to adhesive capsulitis, and atypical numbness or tingling in his hand. *Id.* A cortisone injection was provided, and physical therapy was advised.

Petitioner began physical therapy more than a month later, on March 3, 2020. Ex. 3 at 22. The date of onset is listed as September 27, 2019. *Id.* The provider noted that Petitioner "reported symptoms began after [he] received [a] flu shot last September...." *Id.* He exhibited pain in his left shoulder that radiated down his arm, limited range of motion, and tenderness in the epicondyle area. *Id.* 

Following a stay-at-home order due to the spread of Covid-19, Petitioner continued to perform home exercise, but reported (during a call with his physical therapist on March 30, 2020) that these self-treatment efforts were not improving his symptoms. Ex. 3 at 30.

An electrodiagnostic study was performed on April 8, 2020. Ex. 3 at 9. Petitioner now reported that he had received "a flu shot in the left arm in September 2019, and the same day he had pain in the anterior shoulder [], going down to the hand, and over the next couple of weeks, he had increasing pain with loss of range of motion of the shoulder for abduction." *Id.* The diagnostic examination was normal, and Petitioner was assessed with adhesive capsulitis. *Id.* 

Petitioner returned to Dr. Troy on April 14, 2020. Ex. 4 at 7. Dr. Troy noted that Petitioner had shoulder pain and stiffness "[e]ver since he had the [flu] shot...." *Id.* Further, Petitioner "developed an adhesive capsulitis and a frozen shoulder." *Id.* Additionally, Petitioner was unable to attend physical therapy because his insurance had "unfortunately shut down their therapy with very limited therapy." *Id.* Dr. Troy advised Petitioner to undergo "aggressive home therapy." A second steroid injection was offered

but refused. A telephone follow-up on April 16, 2020, reported ongoing pain. Ex. 3 at 30-31.

On April 24, 2020, Petitioner began acupuncture therapy with Dr. Scott Lee. Ex. 8. Dr. Lee noted that Petitioner had "left shoulder pain ... since he had a vaccination 2 months ago." *Id.* He attended five acupuncture sessions between April 24, 2020, and May 26, 2020. Ex. 8 at 2. His symptoms continued into May (Ex. 4 at 5), and then on June 8, 2020, he had a telehealth visit with Melissa Cartolano, FNP, reporting persistent "issues" with his left shoulder and arm, along with left hand nerve pain "radiating from shoulder intermittently." Ex. 9 at 6.

Petitioner presented to Dr. Peter Dragisic on October 21, 2020, for an annual wellness check. Ex. 9 at 2. Petitioner reported at this time that he "received a flu shot last year, that day his left arm went numb with tingling" and he still had some symptoms. *Id.* Dr. Dragisic noted that Petitioner's shoulder pain was "chronic...after flu vaccination last year." *Id.* 

On December 29, 2020, Petitioner had another follow-up appointment with Dr. Troy. The record notes that Petitioner was "having this incidental induced adhesive capsulitis based on his history given from a flu shot from last year." Ex. 10 at 3. At that time, Petitioner was "doing overall markedly better" but still had some residual symptomatology. He was assessed with "residual adhesive capsulitis that was induced form [sic] a flu shot." *Id.* Petitioner was advised to contact his office if another steroid injection was desired in the future, and he was advised to continue with anti-inflammatory medications. *Id.* at 3-4.

Petitioner submitted an affidavit in support of his claim, signed on December 29, 2020. Ex. 5. Therein, he states that he had a flu vaccine on September 27, 2019, and began feeling pain that same day. *Id.* at 1-2. Petitioner also explained that he did not seek immediate medical attention because he thought the pain would subside. *Id.* at 2.

Sergeant Janine V. Herman, one of Petitioner's coworkers who had a flu vaccination shortly after Petitioner, filed an "Injury On Duty/Witness Report" on February 19, 2020. In it, Sgt. Herman stated that Petitioner had informed her that he was experiencing pain in his left shoulder shortly after receiving the flu vaccination. Ex. 7. Further, "the reason for the delay" in filing the report was because Petitioner "was hopeful that the side effects of [the] vaccination would subside." *Id.* 

# III. Parties' Arguments

Petitioner asserts that he satisfies all legal prerequisites for compensation. Mot. at 10-13. Respondent argues that Petitioner has not established onset within 48 hours of his vaccination, and that pain was not limited to the shoulder in which he received the vaccination. Opp. at 10-12.

### IV. Fact Findings and Ruling on Entitlement

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,<sup>3</sup> a petitioner must establish that he suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

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<sup>&</sup>lt;sup>3</sup> In summary, a petitioner must establish that she received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of her injury for more than six months, died from her injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. See § 11(c)(1)(A)(B)(D)(E).

(iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at \*20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, the Federal Circuit has recently "reject[ed] as incorrect the presumption that medical records are always accurate and complete as to all of the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). Medical professionals may not "accurately record everything" that they observe or may "record only a fraction of all that occurs." *Id.* 

Medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at \*5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

### A. Factual Findings Regarding a Table SIRVA

After a review of the entire record, I find that a preponderance of the evidence demonstrates that Petitioner has satisfied the QAI requirements for a Table SIRVA.

# 1. Petitioner Had No Prior Left Shoulder Condition or Injury

The first requirement for a Table SIRVA is a lack of problems associated with the affected shoulder prior to vaccination that would explain the symptoms experienced after vaccination. 42 C.F.R. § 100.3(c)(10)(i). Respondent does not dispute that Petitioner meets this criterion, and I find that he has demonstrated a lack of history of pain, inflammation, or dysfunction of his left shoulder that would explain his symptoms.

# 2. Onset of Petitioner's Injury Occurred within Forty-Eight Hours of his Vaccination

The medical records preponderantly establish onset of injury close-in-time to vaccination. Petitioner first sought treatment approximately two months after his September 27, 2019 vaccination. In the subsequent timeframe, he consistently reported to treaters that he had experienced symptoms since the vaccination. See, e.g., Ex. 2 at 4 (December 4, 2019, record stating left shoulder pain started "after receiving a flu shot"); Ex. 2 at 2 (December 23, 2019 record stating that Petitioner's pain started "after receiving" flu vaccine); Ex. 4 at 13 (January 7, 2020 record stating that Petitioner's pain "started in September after he received a flu shot...."); Ex. 3 at 9 (April 8, 2020 record stating that Petitioner had "a flu shot in the left arm in September 2019, and the same day he had pain"); Ex. 9 at 2 (October 21, 2020 record stating that Petitioner's symptoms began the same day he received a flu shot).

Respondent argues that Petitioner's statements are vague, and only state his pain began at some unspecified time after receiving the flu vaccination. Opp. at 10-11. But even so, these statements are not *inconsistent* with a proper Table onset (and indeed could be reasonably construed as supporting Table onset). A finding of proper onset can be made based on such a record; Program petitioners are not required to point to records setting forth with chronographic specificity the precise day and hour that their onset manifested.

Further, the relevant medical records show that Petitioner reported shoulder pain "since" the vaccination in a relatively timely manner when measured from the date of vaccination. Thus, Petitioner first began to identify the vaccine as the start of his pain a bit more than two months post-vaccination — not immediately, but not wholly in an attenuated and untimely period either. It is common for SIRVA petitioners to delay seeking treatment, thinking the injury will resolve on its own, especially since patients are often told by medical providers at the time of vaccination to expect some soreness and pain for a period of time after. And individuals also often misconstrue the nature of their injury, and therefore fail to inform treaters of all specific facts relevant to onset until later. Here,

the added detail of onset did not "wait" for months before being provided, but began to be reported in a reasonable time post-vaccination. And Petitioner affirmatively and repeatedly linked his shoulder pain to the September 27, 2019 flu vaccine (Ex. 2 at 2, 4), even specifying that his pain began in September (Ex. 4 at 13), and (later) the same day as his vaccination. Ex. 3 at 9; Ex. 9 at 2. Petitioner's affidavits provide additional corroborating evidence for onset of his injury. Ex. 5 at 1-2.

Accordingly, and based upon the above, I find there is preponderant evidence that establishes the onset of Petitioner's left shoulder pain more likely than not occurred within 48-hours of vaccination.

#### 3. Petitioner's Pain was Limited to his Left Shoulder

Respondent claims that Petitioner cannot establish that his pain was limited to his shoulder because he also reported pain in his left arm, left elbow, and left index finger. Opp. at 10-11. While this contention has better substantiation than Respondent's onset argument, it also fails to rebut Petitioner's Table showing.

The record unquestionably contains reports of non-shoulder pain complaints, but at the same time consistently identifies shoulder pain and loss of range of motion in Petitioner's left shoulder as well. Ex. 2 at 4; Ex. 3 at 9, 22; And this is not a case where the bulk of Petitioner's complaints included an area broader than the shoulder region, or where the shoulder-specific complaints are preponderantly outweighed by other pain occurring elsewhere. Rather, Petitioner's complaints, and the diagnoses, are focused on the shoulder. See, e.g., Ex. 4 at 9 (January 31, 2020, record noting that Petitioner reported pain his elbow, but "the majority of his pain [was] located in the left shoulder.") (emphasis added); id. at 10 (diagnosed with left shoulder pain and adhesive capsulitis); Ex. 3 at 9 (assessing Petitioner with left shoulder adhesive capsulitis).

Admittedly, pain reported in Petitioner's left elbow and finger at times may be unrelated to Petitioner's SIRVA – but that kind of complaint or injury can be disregarded in calculating damages. See Ex. 3 at 9, Ex. 4 at 7 (ruling out other pathology that may have manifested symptoms such as elbow or finger pain). The mere existence of such record complaints does not defeat a showing that Petitioner not only did experience shoulder-specific pain, but that most of his complaints and treatment efforts were aimed at that. Accordingly, preponderant evidence supports this Table element as well.

# 4. There is No Evidence of Another Condition or Abnormality

The last criteria for a Table SIRVA state that there must be no other condition or abnormality which would explain a petitioner's current symptoms. 42 C.F.R. § 100.3(c)(10)(iv). Respondent does not contest this aspect of Petitioner's claim, and there is nothing in the records to suggest that any such condition or abnormality exists.

# **B.** Other Requirements for Entitlement

In addition to establishing a Table injury, a petitioner must also provide preponderant evidence of the additional requirements of Section 11(c). Respondent does not dispute that Petitioner has satisfied these requirements in this case, and the overall record contains preponderant evidence to fulfill these additional requirements.

The record shows that Petitioner received a flu vaccine intramuscularly on September 27, 2019, in the United States. Ex. 1 at 2; see Section 11(c)(1)(A) (requiring receipt of a covered vaccine); Section 11(c)(1)(B)(i)(I) (requiring administration within the United States or its territories). There is no evidence that Petitioner has collected a civil award for his injury. Ex. 5 at 7; Section 11(c)(1)(E) (lack of prior civil award).

Further, onset of Petitioner's left shoulder pain was within 48 hours of vaccination. See 42 C.F.R. § 100.3(c)(10)(ii) (setting forth this requirement). There is also no other condition that would explain Petitioner's current symptoms. 42 C.F.R. § 100.3(a)(XIV)(B). Therefore, Petitioner has satisfied all requirements for a Table SIRVA.

The last criteria which must be satisfied by Petitioner involves the duration of his SIRVA. For compensation to be awarded, the Vaccine Act requires that a petitioner suffer the residual effects of his or her left shoulder injury for more than six months or required surgical intervention. See Section 11(c)(1)(D)(i) (statutory six-month requirement). Here, Petitioner reported pain until at least December 29, 2020, more than six months after his flu vaccination.

Based upon all of the above, Petitioner has established that he suffered a Table SIRVA. Additionally, he has satisfied all other requirements for compensation. I therefore find that Petitioner is entitled to compensation in this case.

# V. Damages

Petitioner requests \$85,000.00 for pain and suffering and \$684.40 in out-of-pocket medical expenses. Mot. at 19. I decline to decide damages at this time. Instead, the

parties are directed to discuss whether damages can be decided informally. If they cannot come to an agreement within 30 days, additional briefing may be ordered.

### Conclusion

In view of the record, I find preponderant evidence that Petitioner satisfies the QAI requirements for a Table SIRVA, and that Petitioner is entitled to compensation.

The parties shall file a Joint Status Report by <u>June 26, 2023</u>, indicating whether settlement discussions are likely to be productive.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran

Chief Special Master